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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,603	03/16/2006	Peter H. Breen		7178

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EXAMINER	
PATEL, NIHIR B	

ART UNIT	PAPER NUMBER
3772	

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10/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,603	BREEN, PETER H.	
	Examiner	Art Unit	
	Nihir Patel	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 21st, 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05.22.2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because it exceeds 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims **1, 3-9, 12, 14 and 15** are rejected under 35 U.S.C. 102(b) as being anticipated by Phillips et al. (US 3,789,837).

5. **As to claim 1,** Phillips teaches an apparatus that comprises an inspiratory flow conduit **38 (see figure 1; column 2 lines 65-67)** for delivering a flow of inspiratory gas to the lungs of the patient; an expiratory flow conduit **42 (see figure 1; column 3 lines 1-5)** for carrying expired gas from the lungs of the patient; a ventilation apparatus **330 (see figures 5 and 6; column 16 lines 25-35)** attached to the inspiratory flow circuit for moving inspiratory gas through the inspiratory

flow conduit toward the lungs of the patient; and a spirometric device **116 (see figures 1 and 2; column 4 lines 50-60)** comprising a chamber, which contains a volume of oxygen and an indicator for indicating changes in the volume of oxygen contained within the chamber, the spirometric device being connected to the ventilation circuit such that the volume of oxygen contained in the chamber will vary relative the volume of oxygen taken up by the patient.

6. **As to claim 3,** Phillips teaches an apparatus that further comprises a valve positioned between the spirometry device and the expiratory flow conduit, the valve being open only during a late portion of the expiratory phase of the ventilation cycle, thereby preventing substantial pressure variations within the spirometic device as a result of inhalation an exhalation **(see column 4 lines 55-67)**.

7. **As to claim 4,** Phillips teaches an apparatus wherein the valve is adapted to be opened and closed in response to control signals and wherein the system further comprises a control device which sends control signals to the valve to cause the valve to open and close at predetermined points on the ventilation cycle **(see column 10 lines 15-25)**.

8. **As to claim 5,** Phillips teaches an apparatus wherein the controller is operative to cause the valve to open at approximately the end of each expiration and to close at approximately the beginning of each inspiration **(see column 10 lines 15-35)**.

9. **As to claim 6,** Phillips teaches an apparatus that further comprises a source of make-up oxygen **29** connected to the ventilation circuit **(see figure 1)**.

10. **As to claim 7,** Phillips teaches an apparatus that further comprises a flow control apparatus for controlling the flow of make up oxygen into the ventilation circuit **(see column 3 lines 15-25)**.

11. **As to claim 8,** Phillips teaches an apparatus wherein the flow control apparatus is adapted to increase or decrease the flow of make-up oxygen into the ventilation circuit in response to control signals and wherein the system further comprises a control device which sends control signals to the flow control apparatus to increase or decrease the flow rate of make-up oxygen into the ventilation circuit **(see column 3 lines 15-25)**.

12. **As to claim 9,** Phillips teaches an apparatus wherein the controller is operative to cause the flow control apparatus to increase or decrease the flow of make-up oxygen as required to prevent more than a predetermined amount of change in the volume of oxygen contained in the cylinder **(see column 3 lines 15-25)**.

13. **As to claim 12,** Phillips teaches an apparatus wherein the chamber moves in relation to the volume of oxygen contained within the chamber and wherein the indicator comprises an indicator of chamber movement **(see column 4 lines 55-67 and column 5 lines 1-10).**

14. **As to claim 14,** Phillips teaches an apparatus wherein the ventilator comprises a bag ventilator, bellows or other manual or automatic ventilating apparatus **(see figures 5 and 6; column 16 lines 25-35)**.

15. **As to claim 15,** Phillips teaches an apparatus wherein the ventilating apparatus returns to the same volume prior to each breath **(see column 16 lines 25-35)**.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18 Claims **10, 11 and 16-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al. (US 3,789,837).

19. **As to claim 16-22,** Phillips substantially discloses a method step of providing a closed ventilation circuit that comprises an expiratory flow conduit for carrying expired gas from the lungs of the patient, a ventilation apparatus attached to the inspiratory flow circuit for moving inspiratory gas through the inspiratory flow conduit toward the lungs of the patient and a spirometric device comprising a chamber which contains a volume of oxygen and an indicator for indicating changes in the volume of oxygen contained within the chamber, wherein the spirometric device is connected to the expiratory flow conduit such that the volume of oxygen contained in the chamber of the spiraometric device will vary relative to the volume of oxygen taken up by the patient; connecting the ventilation circuit to the patient such that the patient will inhale and exhale through the ventilation circuit and determining the change in the volume of oxygen contained in the chamber of the spirometric device as an indication of oxygen uptake by the patient.

The claimed method steps would have been obvious because they would have resulted from the use of the device of Phillips.

20. **As to claims 10 and 11,** Phillips substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a spirometric device that is water sealed spirometer or a dry sealed spirometer. It would have been an obvious matter of design choice to provide a spirometric device that is water sealed spirometer or a dry sealed spirometer, since the applicant has not disclosed that having a water sealed spirometer or dry sealed spirometer solves any stated problems or is for any particular purpose and it appears that the invention would perform equally well with either water, dry or any other type of spirometer as long as it severs its purpose.

21. Claim **2** is rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al. (US 3,789,837) in view of Smargiassi et al. (US 4,727,871).

22. **As to claim 2,** Phillips substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a carbon dioxide absorber connected to the system such that gas from the expiratory flow circuit will pass through the carbon dioxide absorber where carbon dioxide will be removed from the gas and the gas will subsequently flow the carbon dioxide absorber into the inspiratory flow conduit. Smargiassi teaches an apparatus that does provide a carbon dioxide absorber **18** connected to the system such that gas from the expiratory flow circuit will pass through the carbon dioxide absorber where carbon dioxide will be removed from the gas and the gas will subsequently flow the carbon dioxide absorber into the inspiratory flow conduit **(see figure 3)**. Therefore it would have been obvious to one having ordinary skill the art at the time the invention made to modify Phillips invention by providing a carbon dioxide absorber connected to the system such that gas from the expiratory flow circuit will pass through the carbon dioxide absorber where carbon dioxide will be removed from the gas and the gas will

subsequently flow the carbon dioxide absorber into the inspiratory flow conduit as taught by Smargiassi in order to improve the quality of air being delivered to the patient.

23. Claim **13** is rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips et al. (US 3,789,837) in view of Bird et al. (US 3,467,078).

24. **As to claim 13,** Phillips substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a spirometer that has a scale marked on the chamber to indicate the distance by which the chamber has moved. Bird teaches an apparatus that does provide a spirometer that has a scale marked on the chamber to indicate the distance by which the chamber has moved **(see figure 1)**. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was to modify Phillips's invention by providing a spirometer that has a scale marked on the chamber to indicate the distance by which the chamber has moved as taught by Bird in order to determine and provide accurate flow rate of the patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit 3772

Nihir Patel

MICHAEL A. BROWN
PRIMARY EXAMINER